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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,945	10/04/2001	J. Christopher Flaherty	59249-024 (INSL-113)	3499

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01/06/2004

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EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 01/06/2004

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,945

Applicant(s)

FLAHERTY ET AL.

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,33-36,48-59,67 and 74-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,33-36,48-59,67 and 74-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12-15,20.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-7, 33-36, 48-51, 55-59, 73-81, and 85-89 are rejected under 35 U.S.C. 102(e) as being anticipated by Lebel et al. (USPub 2003/0065308).

Lebel et al. discloses a system for delivering fluid comprising a fluid delivery device, an exit port, a dispenser, a local processor and a local communication element, as well as a remote control device separate from the fluid delivery device, and at least one data collection assembly adapted to measure, monitor, calculate, and store a physiologic parameter of a patient. (Entire reference)

As to claims 2-7, wherein the data collection assembly includes a sensor to measure blood glucose for blood.

As to claims 33-36, wherein the data collection assembly is adapted to be worn on an arm of the patient, and wherein the exit port assembly includes a transcutaneous access tool, which is a needle. (Entire reference)

As to claims 55-59, wherein the local processor of the fluid delivery device is programmed to provide flow information, the local communication unit includes a

wireless transmitter for transmitting the flow information from the local processor, the remote control device includes a remote receiver for receiving the flow information from the local transmitter, and the user interface components of the remote control device include output components connected to the remote processor for allowing a user to receive the flow information. (Entire reference)

3. Claims 1-7, 33-36, 48-51, 55-59, 73-81, and 85-89 are rejected under 35 U.S.C. 102(e) as being anticipated by Causey et al. (USPN 6,641,533).

Causey et al. discloses a system for delivering fluid comprising a fluid delivery device, an exit port, a dispenser, a local processor and a local communication element, as well as a remote control device separate from the fluid delivery device, and at least one data collection assembly adapted to measure, monitor, calculate, and store a physiologic parameter of a patient. (Entire reference)

As to claims 2-7, wherein the data collection assembly includes a sensor to measure blood glucose for blood. (Entire reference)

As to claims 33-36, wherein the data collection assembly is adapted to be worn on an arm of the patient, and wherein the exit port assembly includes a transcutaneous access tool, which is a needle. (Entire reference)

As to claims 55-59, wherein the local processor of the fluid delivery device is programmed to provide flow information, the local communication unit includes a wireless transmitter for transmitting the flow information from the local processor, the remote control device includes a remote receiver for receiving the flow information from the local transmitter, and the user interface components of the remote control device

include output components connected to the remote processor for allowing a user to receive the flow information. (Entire reference)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-7,33-36,48-59,67 and 74-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Portner et al. (USPN 4,265,241) in view of. Lebel et al. or Causey et al. as applied to claims above.

Portner et al. discloses an infusion pump that works by telemetry and has a pressurized reservoir, an accumulator with valve means, and a refillable port. (Figures 1, 5-8 and entire reference), but fails to disclose the local and external processor and output components.

Lebel et al. disclose a medical device with a remote control system and a medical infusion pump. (See above)

Causey et al. disclose a medical device with a remote control system and a medical infusion pump. (See above)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine Portner et al. with either Lebel et al. or Causey et al. because Lebel et al. and Causey et al. used a standard pump and therefore anything well known in the pump art would be an obvious modification, such as pressurized reservoir, an

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accumulator with valve means, and a refillable port. Lebel et al. and Causey et al. both teach a more effective way to deliver treatment to the patient as well as to control and input information to the pump because of the remote means as described in both Lebel et al. and Causey et al. Therefore, it would have been obvious to combine Portner et al. with Lebel et al. or Causey et al.

Response to Arguments

6. Applicant's arguments, see Paper number 19, filed 10/22/03, with respect to the rejection(s) of claim(s) under Gonnelli et al. and Kriesel et al. have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.



Matthew DeSanto
Art Unit 3763
December 29, 2003



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